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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,558	08/27/2001	Lixiao Wang	S63.2-9482	4996
490	7590	06/18/2004	EXAMINER	
VIDAS, ARRETT & STEINKRAUS, P.A. 6109 BLUE CIRCLE DRIVE SUITE 2000 MINNETONKA, MN 55343-9185			BRUENJES, CHRISTOPHER P	
			ART UNIT	PAPER NUMBER
			1772	

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/940,558		WANG, LIXIAO	
	Examiner		Art Unit	
	Christopher P Bruenjes		1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-58 and 63-76 is/are pending in the application.
- 4a) Of the above claim(s) 14-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 10, 2004 has been entered.

WITHDRAWN REJECTIONS

2. The 35 U.S.C. 112 rejections and objection to the specification of record in the Office Action mailed November 20, 2003, Pages 3-6 Paragraphs 6-8, have been withdrawn due to Applicant's amendments in the Paper filed April 23, 2004.

3. The 35 U.S.C. 103 rejections of claims 1, 2, 4, 9-13, and 59-60 over Saitou et al in view of Lunk et al of record in the Office Action mailed November 20, 2003, Pages 7-10 Paragraph 9, have been withdrawn due to Applicant's amendments in the Paper filed April 23, 2004.

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4. The 35 U.S.C. 103 rejections of claims 7-8 and 61-62 over Tomaschko in view of Lunk of record in the Office Action mailed November 20, 2003, Pages 10-13 Paragraph 10, have been withdrawn due to Applicant's amendments in the Paper filed April 23, 2004.

NEW REJECTIONS

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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5. Claims 63-67 and 70-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saitou et al (USPN 6,451,005) in view of Smith et al (USPN 6,531,559).

Saitou et al teach a medical tube comprising a tube that is a catheter, catheter shaft, or catheter balloon (see abstract), comprising a first layer and second layer, wherein the second layer is extruded polytetrafluoroethylene (col.9, 1.56-62). The first layer comprises a fluorocarbon resin including either polytetrafluoroethylene or a perfluoroalcoxy resin (or perfluoroalkyl resin), which includes perfluoroalcoxy vinyl ether with polytetrafluoroethylene, known as PFA, which is a perfluoroalcoxy resin (col.13, 1.48-58). The first and second layers are extruded, therefore the layers are melt-processible (col.14, 1.32-37 and col.15, 1.18-21). The first and second layers are either polytetrafluoroethylene or one of the other thermoplastic resins such as perfluoroalcoxy resin or polyamide. The outer layer flows into the gap between the adjacent windings of the coil and adhere to the periphery of the inner layer. In this way the inner and outer layer contact each other (col.15, 1.7-11). Therefore because the inner or outer layer is the first or second layer reversibly, then the polytetrafluoroethylene contacts the inner side of the first

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layer in one embodiment and the outer side of the first layer in another embodiment.

Saitou et al fail to explicitly teach the melt flow index value of the extruded or melt-processible poly(tetrafluoroethylene). However, Smith et al teaches that PTFE that is not melt-processible cannot be molded by regular extrusion as the PTFE of Saitou et al is extruded, and that methods other than common melt-processing such as extrusion are less economical and limit the types and characteristics of objects and products manufactured with PTFE (col.1, 1.60-67). Smith et al further teaches that any polymer including PTFE that is melt-processible exhibit a melt flow index value greater than zero and less than 2.5 g/10min (col.5, 1.40-42). Smith et al also teaches that the elongation of break of is at least 10%, the melt temperature is at least 320°C and the crystallinity is between 1 and 60% (col.3, 1.20-36 and 63-65), in order for the melt-processible PTFE to be melt-processible but still maintain good mechanical properties inherent to common PTFE (col.3, 1.15-20). One of ordinary skill in the art at the time the applicant's invention was made would have recognized that melt-processible PTFE preferably has a melt flow index value greater than 0 and less than 2.5 g/10min, an elongation of break of at

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least 10%, a melt temperature of at least 320°C and crystallinity between 1 and 60%, as taught by Smith et al.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to select the melt-processible PTFE composition of Saitou et al to fit the properties of the melt-processible PTFE composition of Smith et al, in order to balance the need for a melt flow index greater than zero for melt-processing without sacrificing the good mechanical properties of PTFE, as taught by Smith et al.

6. Claims 68-69 rejected are under 35 U.S.C. 103(a) as being unpatentable over Saitou et al in view of Smith et al as applied to claim 63 above, and further in view of Garabedian et al (USPN 6,508,805).

Saitou et al and Smith et al teach all that is claimed in claim 63 as shown above, but fails to explicitly teach a third layer. However, Garabedian et al teach that polytetrafluoroethylene is required on both the innermost and outermost layer of a medical tube, because of its biocompatibility and lubricious behavior (col.4, 1.4-14 and col.7, 1.25-26). Saitou et al and Smith et al teach that the inner layer is preferably polytetrafluoroethylene, but teaches

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that the other layer is any flexible polymer. One of ordinary skill in the art would have recognized that a third layer is added to a medical tube to ensure that a polytetrafluoroethylene layer is present on both the innermost and outermost layers, because of its biocompatibility and lubricious behavior.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to extrude a third layer composed of polytetrafluoroethylene having the properties of Smith et al to the outside of the outer layer of Saitou et al for the same reasons as the inner surface in order to improve the biocompatibility and lubricious behavior of the outside of the medical tube, which is important when using the medical tube as a catheter inserted into a human body, as taught by Garabedian et al.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fukumoto (USPN 5,944,937); Krause et al (USPN 5,916,404); Effenberger et al (USPN 5,141,800).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to

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Christopher P Bruenjes whose telephone number is 571-272-1489.

The examiner can normally be reached on Monday thru Friday from 8:00am-4:30pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher P Bruenjes
Examiner
Art Unit 1772

CPB

June 10, 2004


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

6/14/04